DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
U.S. Agent/Director Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

January 9, 2015

Re: K143225
Trade/Device Name: INFX-8000V with Wireless Footswitch
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: II
Product Code: OWB, JAA
Dated: December 9, 2014
Received: December 10, 2014

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143225

Device Name
INFX-8000V with Wireless Footswitch

Indications for Use *(Describe)*
This device is a digital radiography/fluoroscopy system use in a diagnostic interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. CLASSIFICATION and DEVICE NAME:

Classification Name:	**Image Intensified Fluoroscopic X-ray System**
Regulation Number:	**21 CFR 892.1650 (Class II)**
Product Code	**OWB – Interventional Fluoroscopic X-ray System** **JAA – System, x-ray, fluoroscopic, image-intensified**
Trade Proprietary Name:	**Infinix**
Model Number:	**INFX-8000V, with wireless footswitch**

2. ESTABLISHMENT REGISTRATION: 9614698

3. CONTACT PERSON, U.S. AGENT and ADDRESS:

Contact Person/U.S. Agent:
Paul Biggins
Director, Regulatory Affairs
(714) 730-5000
Fax: (714) 730-1310
pbiggins@tams.com

Establishment Name and Address:
Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, Ca. 92780

4. MANUFACTURING SITE
Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan
CONTACT: AKINORI HATANAKA

5. Date OF SUBMISSION:
November 12, 2014

6. PERFORMANCE STANDARD:
21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

7. PREDICATE DEVICE:
INFX-8000V,v5.30 (K133535)

8. REASON FOR SUBMISSION:
Modification of a cleared device

9. SUBMISSION TYPE:

Special 510(k)

10. DEVICE DESCRIPTION:

This device in an x-ray system that is capable of radiographic and fluoroscopic studies and is used in an interventional setting. The system consists of a C-arm, which is equipped with an x-ray tube, beam limiter and x-ray receptor, x-ray controller, computers with system and processing software, and a patient radiographic table.

11. Indication for Use:

This device is a digital radiography/fluoroscopy system used in a diagnostic and interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.

12. SUMMARY OF CHANGE(S)

This device has been modified to use an interchangeable BlueTooth wireless footswitch. The introduction of this footswitch does not change any hardware or software requirements of the cleared device.

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the INFX-8000V, v5.30 K133535, marketed by Toshiba America Medical Systems. The basic system configuration, method of operation, base software and manufacturing process remain unchanged from the cleared device. There are no new indications for use or intended use of the device.

14. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 standards, its collateral standards and particular standards; IEC 60601-2-43 and IEC60601-2-28. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

15. CONCLUSION

Based upon the results of the verification testing the performance of the modified device is equal to or better than the predicate device. The addition of the wireless footswitch does not change the indications for use or the intended use of the device. Safety and effectiveness have been verified via risk management and application of design controls to the modification. Toshiba concludes that it has demonstrated that the modified INFX-8000V is substantially equivalent to the previous version.